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Innovative Therapy and the Law: the novel issues raised by the case of Charlie Gard
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Abstract

The application by Great Ormond Street Hospital to court in respect of the future medical treatment of Charlie Gard was novel in that the Trust sought not only a declaration that it was lawful and in Charlie's best interests to withdraw ventilation but further that it was not in Charlie's best interests to be administered with an innovative therapy which had the effect of preventing a doctor in another hospital from administering it to him. It is not uncommon for parents to seek for novel, innovative, pioneering, or experimental treatment to be given to a seriously ill child although, to date, there have been few cases on this issue before the courts. Whilst parents are given a large degree of freedom to raise their children as they consider appropriate, limits have to be imposed upon what parents can demand their children are subjected to. All courts, from the Family Division of the High Court through the domestic appeal courts to the European Court of Human Rights and back to the Family Division of the High Court, affirmed the application of the best interests principle in such cases. In this article it is argued that the law should set those limits not merely according to the best interests of the individual child but also by whether the therapy is supported by a reasonable and competent body of professional opinion and in accordance with good medical practice.

Introduction

The recent case of Charlie Gard raised questions about the pursuit by parents of innovative, novel, pioneering or experimental therapy for a seriously ill child. Whilst his treating clinicians, at Great Ormond Street Hospital, considered the therapy to be futile a doctor in the US, Professor Hirano, told the court in the first hearing that he was prepared to trial the therapy. Convinced that this was a viable alternative therapy, his parents refused to accept the judgment of Francis J in the High Court in April 2017 that it was in Charlie's best interests for ventilation to be withdrawn and palliative care provided. They did not accept that the judge was better placed than they, his parents who knew Charlie best, to make decisions about his best interests. Whilst the offer of a trial of the therapy remained his parents appealed through the courts in the attempt to secure it for him. The facts of the case and the arguments made on appeal raise important questions about the legal duties of professionals and of NHS Trusts when parents are seeking novel, pioneering, innovative, or experimental therapy to be administered to their child. I argue that in such cases the courts should adopt the approach taken in the earlier case of *Simms* also concerned with innovative therapy. In that case, Butler-Sloss P first considered whether the therapy was supported by a competent body of professional opinion, then assessed whether administration of the therapy was in the best interests of the patients and finally whether it could be provided by the NHS. This approach, I argue, ensures that the medical evidence is clear to all who have the responsibility to determine the best interests of a seriously ill child.

This article first outlines the facts of the Charlie Gard case, the novel issues raised and the arguments presented on appeal. It then considers, within the context of the arguments made before the Court of Appeal, the limits the law places upon the exercise of parental responsibility with respect to the medical treatment of a child. The approach adopted to the question of the administration of innovative therapy by Butler-Sloss P in *Simms*¹ is explained and that approach applied to the facts of the Charlie Gard case. Whilst this approach would not have led the judge to a different conclusion, it would have ensured that the court had

* I would like to thank the journal editors and referees for their comments and suggestions on an earlier draft of this article.

¹ *Donald Simms and Jonathan Simms v An NHS Trust and Secretary of State for Health; PA and JA v An NHS Trust and Secretary of State for Health* [2002] EWHC 2734.

before it, and the parents understood, the clinical reasons those responsible for Charlie's medical treatment at GOSH considered it to be ethically wrong, and not in his best interests, to maintain Charlie's life by mechanical ventilation for a trial of the therapy.

The novel issue for the law in the Charlie Gard case

Charlie Gard appeared to be a normal healthy baby when he was born in August 2016. At eight weeks old, he was admitted to hospital and transferred to the care of Great Ormond Street Hospital for Sick Children (GOSH) where he remained on a ventilator and fed by naso-gastric tube for the rest of his short life. Charlie was diagnosed with an extremely rare, inherited, progressive, condition, mitochondrial depletion syndrome, RRM2B. Mitochondrial conditions affect the generation of the energy supply of cells² in Charlie's case affecting his ability to move, breathe, neurological functioning, and hearing.

His parents, Connie Yates and Chris Gard, wanted him to have a trial of nucleoside bypass therapy. This was innovative therapy which had never been administered to a child with the form of mitochondrial depletion syndrome which Charlie had nor had it been tried in humans or tested on mice.³ There was no prospect of a cure but his parents believed it offered a chance of improving the length and quality of his life.⁴ His clinical team prepared an application to the GOSH Rapid Response Clinical Ethics Committee seeking approval for a trial of the therapy. In January 2017, before the application could be made, the frequency of Charlie's seizures increased and his clinicians considered he had sustained severe and irreversible brain damage. As a consequence, his clinicians concluded that the burdens of everyday living outweighed the benefits and that it was not in his interests to be maintained on a ventilator, with associated pain and suffering, for the administration of therapy which was of uncertain benefit. Second opinions from 'world leading authorities' supported their conclusion that withdrawal of life-sustaining treatment was reasonable and in accordance with Royal College of Paediatrician and Child Health (RCPCH) guidelines.⁵ His parents rejected his doctors' assessment of the severity of his brain damage, refused their consent to the withdrawal of ventilation and maintained the view that he should be given the chance of benefitting from nucleoside therapy. Commencing the lengthy legal battle, GOSH applied to court for a declaration under its inherent jurisdiction and a Specific Issue Order under s.8 of the Children Act 1989 that it was lawful, and in Charlie's best interests, not to be given nucleoside therapy and that it was lawful to withdraw ventilation and provide palliative care.

Judges are regularly asked by Trusts to decide whether it is lawful, and in the best interests of a child, for life-sustaining treatment to be withdrawn or withheld.⁶ The novel question for

² Department of Health, *Mitochondrial Donation: A consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child*, February 2014, 1.4.

³ Francis J explained that as a consequence he viewed the therapy to be experimental rather than pioneering, *GOSH v Yates & Gard* [2017] EWHC 972, [49]. I have used the terminology of innovative therapy following Brierley and Larcher who defined innovative therapy as 'any newly introduced treatment, or a new modification to an existing therapy with unproven efficacy and side effect profile, which is being used in the best interests of a patient, often on an experimental and/or compassionate basis,' Joe Brierley and Vic Larcher, 'Compassionate and innovative treatments in children: a proposal for an ethical framework' (2009) 94 Arch Dis Child 651-654, <http://nnpdf.org/files/2016/11/Compassionate-Use-in-Children.pdf> [last accessed 26/9/17].

⁴ *GOSH v Yates & Gard* [2017] EWHC 972, [107-112].

⁵ *Ibid*, [60] referring to the RCPCH framework for good medical practice, *Making decisions to limit treatment in life-limiting and life-threatening conditions in children: a framework for practice*, 2015, (2015) Archives of Diseases in Childhood 1-23, doi: 10.1136/archdischild-2014-306666 [last accessed 27/9/17].

⁶ In the months when questions about Charlie's future medical treatment were before the courts, April-July 2017, there were three such cases decided by the High Court and reported on Baillii;

the court on Charlie's future medical treatment was whether it was lawful, and in Charlie's best interests, for him **not** to be administered with innovative therapy. The declarations the court was asked to make were thus unprecedented in that they not only addressed the legality of the care plan the GOSH clinicians considered to be in Charlie's best interests, to which his parents could not agree, but further had the effect of preventing the administration of innovative therapy by a clinician in another hospital who was offering to provide it.

At the first hearing, in April 2017, Counsel for Charlie's parents, Sophia Roper, with reference to *Simms* (considered below),⁷ pointed to the novel issues raised by the dispute between his parents and clinicians in that there were no previous 'cases where life-sustaining treatment has been withdrawn, even from a profoundly disabled child with a desperately poor quality of life, where there is an available treatment which has the potential materially to improve that quality of life'.⁸ Francis J first assessed the evidence upon Charlie's quality of life and then the chances of the therapy improving his quality of life. The evidence at the first hearing of the case in April led Francis J to the conclusion that Charlie's 'quality of life was not one that should be sustained without hope of improvement' and that the consensus of the doctors who had examined Charlie was that nucleoside therapy was 'futile'.⁹ The judge made the declarations sought by the Trust having concluded that it was not in Charlie's best interests to undergo a trial of the therapy or for ventilation to be continued, a view shared by the Guardian who was appointed by the court to provide independent representation of Charlie's interests.

In the Court of Appeal Counsel for Charlie's parents, Richard Gordon QC, adopted a different approach to this novel question.¹⁰ Drawing upon the case of *King* (considered below),¹¹ the submission was that where there is an alternative viable therapeutic option to that proposed by the treating clinicians, parental preference should be followed except in those cases where it is likely to cause the child 'significant harm'.¹² In reply Katie Gollop QC for GOSH submitted that the 'established yardstick' was best interests and there was no 'justification for this court to endorse the creation of a sub-set of cases based upon establishing significant harm'.¹³ In his leading judgment, rejecting the submission, McFarlane LJ concluded that the authorities demonstrated that there is no 'factor or filter' before the court evaluates the best interests of the child.¹⁴ Furthermore, that as the judge had found that administration of nucleoside therapy would be futile, be of no benefit and merely prolong, in McFarlane LJ's words, Charlie's 'awful existence',¹⁵ there was no viable alternative before the court.¹⁶ Finally, although it had not been addressed in the court below, McFarlane LJ considered that had Francis J been invited to find whether Charlie was currently suffering significant harm he would have so concluded¹⁷ and, it followed, significant harm would result from the continuation of ventilation and Charlie's

A Local Authority and An NHS Trust v MC & FC & C [2017] EWHC 370; *GOSH v NO & KK & MK* [2017] EWHC 241; *An NHS Hospital Trust v GM, DK and HK* [2017] EWHC 1710. *An NHS Trust v BK, LK & SK* [2016] EWHC 2860 was decided in November 2016 but publication of the judgment of MacDonald J was delayed until April 2017 to avoid having to ask the child's parents whether the judgment should be published immediately following the death of their son.

⁷ *Supra*, n 1.

⁸ *Supra*, n 4, [124].

⁹ *Ibid*, [126].

¹⁰ In the first hearing before the High Court, Charlie's parents were represented by Sophia Roper instructed by Bindmans LLP; before the Court of Appeal they were represented by Richard Gordon QC, Gerard Rothschild and Grant Armstrong instructed by Harris Da Silva.

¹¹ *In the Matter of Ashya King* [2014] EWHC 2964.

¹² *In the Matter of Charles Gard* [2017] EWCA Civ 410, [58].

¹³ *Ibid*, [74].

¹⁴ *Ibid*, [94].

¹⁵ *Ibid*, [97].

¹⁶ *Ibid*, [97].

¹⁷ *Ibid*, [114].

life in order to administer nucleoside therapy.¹⁸ Thus, the court found that the submissions could not be supported as a matter of fact rendering irrelevant the question of a distinction in law. The second ground of appeal, also dismissed, was that GOSH had no standing to prevent the US team from administering the therapy, to seek to do so was beyond the powers of the hospital as a public authority and in the absence of significant harm outside the court's jurisdiction.¹⁹ The submission was that whilst the Trust could apply to court and the court could make a declaration that it was lawful for the Trust's clinicians not to provide nucleoside therapy, the Trust could not seek to prevent the parents seeking the treatment elsewhere. The Court of Appeal dismissed the appeal preferring the submission of Ms Gollop QC that the issue had arisen between the parents and the clinicians which the Trust had properly brought before the court for a judge to decide according to the best interests of the child.²⁰ The Supreme Court rejected the parents' application for permission to appeal determining that it did not raise an arguable point of law.²¹ The European Court of Human Rights deemed the parents' application inadmissible.²² English law did not breach the Article 2, 5, 6 or 8 rights of Charlie's parents. The courts thus affirmed the approach which has been developed at common law primarily through decisions of courts of first instance. The appeal process was thus exhausted but in July 2017, at the request of Charlie's parents, GOSH returned to the High Court for evaluation of what his parents hoped amounted to new medical evidence. But, after further tests which revealed the extent of Charlie's muscle deterioration, Charlie's parents accepted that the therapy no longer offered him a chance of any improvement and withdrew their opposition to the orders.²³ Francis J made declarations about Charlie's end of life care upon which his parents and GOSH were unable to agree. Charlie was moved to a hospice, ventilation withdrawn, and he died, minutes later, a week before his first birthday.

The Limits of Parental Responsibility

Charlie's parents expressed the view that their parental rights had been removed from them by the actions of GOSH and then the decisions of the court which had the effect of preventing them from taking Charlie to America for innovative therapy. The GOSH position statement in July submitted that:

'Charlie's parents fundamentally believe that they alone have the right to decide what treatment Charlie has and does not have. They do not believe that Great Ormond Street should have had the right to apply to the Court for an independent, objective decision to be made. They do not believe that there is any role for a judge or a court. They believe that only they can and should speak for Charlie and they have said many times that they feel they have been stripped of their rights as parents'.²⁴

Whilst Charlie's parents deployed the discourse of parental rights rather than responsibilities, their claim was one which reflects the position in law, which is that the primary responsibility for children rests with their parents rather than the state. Parents do have legal obligations, for example, to ensure the child receives an appropriate education²⁵ and to seek medical

¹⁸ *Ibid*, [115].

¹⁹ *Ibid*, [84].

²⁰ *Ibid*, [88], [117].

²¹ *In the matter of Charlie Gard (Permission to Appeal Hearing)*, 8 June 2017, <https://www.supremecourt.uk/news/permission-to-appeal-hearing-in-the-matter-of-charlie-gard.html> [last accessed 27/9/17].

²² *Charles Gard and Others v United Kingdom*. Application no. 39793/17, 28 June 2017, [http://hudoc.echr.coe.int/eng#{"documentcollectionid2":\["DECGRANDCHAMBER"\],"ADMISSIBILITY":\["ADMISSIBILITYCOM"\],"itemid":\["001-175359"\]}](http://hudoc.echr.coe.int/eng#{) [last accessed 27/9/17].

²³ *Re Gard (A Child)* [2017] EWHC 1909.

²⁴ GOSH's position statement of the 13th July, [7], <https://www.serjeantsinn.com/news/charlie-gard-position-statements/> [last accessed 27/9/17].

²⁵ Education Act 1996, ss.7-8.

treatment for a sick child.²⁶ Yet, the law gives parents ‘a large measure of autonomy in the way in which they discharge their parental responsibilities’²⁷ from routine day-to-day matters to important decisions which will have major consequences for the child’s life. This is why the Children Act 1989 imposes a threshold before the court can consider whether it is in the welfare of the child for public law care orders to be made. The threshold, set out in section 31(2), is that the child is suffering, or is likely to suffer, significant harm attributable to ‘(i) the care given to the child, or likely to be given to him if the order were not made, not being what it would be reasonable to expect a parent to give to him; or (ii) the child’s being beyond parental control.’ So whilst the primary responsibility for the care of children rests with their parents and parents have a large degree of freedom as to how they raise their children, limits are placed upon parental discharge of their responsibilities in the interests of child protection and welfare.

Decisions about a child’s medical treatment are made in the exercise of parental responsibility held in Charlie’s case by his mother and father. Parental responsibility is defined in section 3(1) of the Children Act as ‘all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.’²⁸ In the context of a child’s medical treatment, this has been framed as a parental right which is subject to the welfare of the child. Holders of parental responsibility are required to ‘adopt a child centred approach to their responsibilities in meeting the child’s welfare’.²⁹ As Ward LJ said in the conjoined twins case, *Re A*, ‘Since the parents have the right in the exercise of their parental responsibility to make the decision, it should not be a surprise that their wishes should command very great respect. Parental right is, however, subordinate to welfare.’³⁰ In the majority of cases, parents will work together with the clinicians responsible for their child’s care, together agreeing upon the treatment, from the options available, that they consider to be in the best interests of the child, altering the treatment plan in response to the specific needs of the individual child. Where parents and clinicians cannot agree upon a treatment plan, the welfare of the child requires the Trust to refer the dispute to court. The responsibility is then that of the judge to make an independent, objective, decision on the evidence as to the child’s best interests.

Before the Court of Appeal, Counsel for Charlie’s parents submitted that in the context of the agreed preferences of holders of parental responsibility as to the medical treatment that was in the best interests of their child the limit placed upon the exercise of parental responsibility was that of a risk of significant harm. In making this submission Mr Gordon QC was not seeking to bracket the case with public law care proceedings but to align it, as an exception in the body of case law over the past forty years, with the case of *King*. The submission was grounded in the words of Baker J in that case when he said,

‘In most cases, the parents are the best people to make decisions about a child and the State – whether it be the court, or any other public authority – has no business interfering with the exercise of parental responsibility unless the child is suffering or is likely to suffer significant harm as a result of the care given to the child not being what it would be reasonable to expect a parent to give.’³¹

On the facts of the case before him, Baker J concluded that the state had rightly interfered with the exercise of parental responsibility when Ashya had been removed by his parents from specialist care at a time when he urgently needed post-operative treatment. At that time, the

²⁶ Children and Young Persons Act 1933, s.1.

²⁷ *Regina v Secretary of State for Education and Employment and Others* [2005] UKHL 15, [72].

²⁸ It was accepted in *In Re W (A Minor) (Medical Treatment: Court’s Jurisdiction)* [1993] Fam 64, 78, that decisions about a child’s medical treatment come within parental responsibility.

²⁹ *Re C (children)* [2016] EWCA Civ 374, King LJ [43], quoting Sharpe J in the Family Court.

³⁰ *In Re A (Children) (Conjoined Twins: Surgical Separation)* [2001] Fam 147, 193.

³¹ *Supra*, n 11, [31].

hospital and local authority believed that his parents did not have the supply of food or energy required for the administration of his naso-gastric feed nor the skills to ensure its safe provision. Consequently, the local authority had applied for Ashya to be made a ward of court given reasonable grounds to believe that Ashya was at risk of suffering significant harm. The treatment Ashya's parents thought was best for him, Proton Beam Therapy following surgery to remove a malignant brain tumour, was innovative and unproven in children with Ashya's condition. The doctors at Southampton did not consider Proton Beam Therapy to be a worse option than conventional treatment but neither did they think it offered any benefits over conventional radiotherapy. At the time Proton Beam Therapy was not available in the UK and funding for treatment abroad had been refused in accordance with NHS England guidance.³² By the time the matter was before Baker J in wardship proceedings, the judge was able to conclude that there was a reasonable and coherent alternative treatment plan for the provision of the post-operative care with funding and transport arrangements in place not opposed by the local authority, CAFCASS or the Trust.³³ Baker J gave permission for Ashya to be taken to Prague for the treatment and ordered that wardship be discharged upon his admission.

Having analysed Baker J's judgment in *King*, McFarlane LJ concluded that it provided no basis for holding that 'any test based on significant harm is to be applied to cases relating to the medical treatment of children'.³⁴ This view was upheld by the Supreme Court. The legal principle for decisions about a child's medical treatment was best interests and not the absence of significant harm. Yet, Charlie's parents continued to believe that it was in their son's best interests to try innovative therapy which a doctor in the US was willing to administer.

Innovative Therapy

To date, there are few reported cases concerning the provision of innovative therapy to children. The first, in 1995, concerned an application by the father of Jaymee Bowen for judicial review of the Health Authority's decision not to fund an extra-contractual referral for further treatment against leukaemia. Jaymee had relapsed after a period in remission following treatment for acute myeloid leukaemia as a secondary cancer following treatment for non-Hodgkin's lymphoma.³⁵ Jaymee's doctors had concluded that it was not in Jaymee's best interests to be given the treatment, donor lymphocyte infusion, described in the judgment as at the 'frontier of medical science'.³⁶ Her doctors thought that it was in her best interests to be given palliative care, minimising pain and suffering with the aim of enabling her to enjoy what remained of her life. As a judicial review of a funding decision, the court neither addressed whether the treatment was supported by a competent body of professional opinion nor whether it was in Jaymee's best interests to have further treatment or palliative care. Following media publicity of the unsuccessful challenge to the decision in the courts, Jaymee's treatment was funded by an anonymous donor. Jaymee went into remission but died just over a year after the treatment commenced.

A better comparison than either *King*, in which the medical issue had been resolved, or *Bowen*, as judicial review of the health authority's funding decision, is the case of *Simms*. Whilst unusual in the jurisprudence in that the application for a declaration of the court in the exercise of its inherent jurisdiction was made by the parents, that is of no distinction as once the matter is referred to court, by a party with an interest in the child's welfare, the duty of the judge is to decide it. The court was asked to approve the administration of unlicensed therapy to two teenagers, one eighteen and one sixteen years old, both of whom had been rendered

³² *Ibid*, [9-10].

³³ *Ibid*, [33].

³⁴ *Supra*, n 12, [104].

³⁵ *R v Cambridge District Health Authority, ex parte B* [1995] 1 FLR 1055. The case is critiqued by Chris Ham & Susan Pickard, *Tragic Choices in Health Care: The case of Child B*, King's Fund, 1998 and detailed in Sarah Barclay, *Jaymee; The Story of Child B*, 1996.

³⁶ *Ibid*.

incompetent, entirely dependent and ‘helpless invalids lying in a bed and with a severely limited enjoyment of life’ by probable variant Creutzfeldt-Jakob disease (vCJD). Told there was no cure for vCJD the father of the eighteen year-old, later identified as Jonathan Simms, found on the internet details of Japanese research into the therapy. In his evidence to the court, he explained that if the case went against them they would ‘search the world to get treatment elsewhere, including going to have the treatment in Japan’.³⁷ Butler-Sloss P was asked to approve the unlicensed therapy, described at various points in the judgment as ‘innovative’, ‘experimental’, ‘pioneering’, in which PPS (Pentosan Polysulphate) infusions would be administered, following a surgical procedure, directly into the brain. Research had been carried out in different species and it was not known whether it would work in humans or on vCJD.³⁸ The risks and benefits of the therapy to the teenagers both of whom had severe brain damage, yet were considered to experience both pleasure and pain, was unknown.³⁹ Butler-Sloss P followed the approach she had adopted in *In re A (Male Sterilisation)*,⁴⁰ a case concerned with the sterilisation of an incompetent adult in which she first identified the viable options accepted as proper by a competent body of professional opinion before determining which of the viable options was in the best interests of the patient. Thus, the judge first asked whether there was a competent body of professional opinion within the United Kingdom which supported the therapy, subject to the risks and benefits of the therapy, before considering whether it was in the best interests of the teenagers to receive it.⁴¹

As John Harrington has observed,⁴² Butler-Sloss P applied a ‘fairly weak’ version of the *Bolam*⁴³ test based on the absence of negative opinions. The judge said that the *Bolam* test should not operate so as to ‘inhibit medical progress’ observing that if *Bolam* had to be ‘complied with to its fullest extent’ then no innovative treatment or procedures could be tried.⁴⁴ Having considered the three medical English experts and the research of the Japanese neuropathologist, the judge was ‘satisfied, consistent with the philosophy that underpins the *Bolam* test [1957] 1 WLR 582, that there is a responsible body of relevant professional opinion which supports this innovative treatment.’⁴⁵ Butler-Sloss P then assessed the risks and benefits to determine whether the responsible body of opinion was ‘capable of withstanding logical analysis’.⁴⁶ There were risks from the surgery, general anaesthetic and the infusion. Butler-Sloss P considered the benefits to be harder to assess. However, the judge explained that she considered benefit to a patient who will not recover to include improvement from their current condition, continuation in their current condition without deterioration for longer than may have been the case, and prolongation of life for longer than might otherwise have been.⁴⁷ In the judge’s view,

‘Where there is no alternative treatment available and the disease is progressive and fatal, it seems to me to be reasonable to consider experimental treatment with unknown benefits and risks, but without significant risks of increased suffering to the patient, in cases where there is some chance of benefit to the patient.’⁴⁸

³⁷ *Supra*, n 1, [5].

³⁸ *Ibid*, [22].

³⁹ *Ibid*, [4], [7].

⁴⁰ *In re A (Male Sterilisation)* [2000] 1 FLR 549.

⁴¹ *Supra*, n 1, [51].

⁴² John Harrington, ‘Deciding Best Interests: Medical Progress, Clinical Judgment and the “Good Family”’ [2003] 3 Web JCLI.

⁴³ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

⁴⁴ *Supra*, n 1, [48].

⁴⁵ *Ibid*, [51].

⁴⁶ *Bolitho v City and Hackney Health Authority* [1998] AC 232.

⁴⁷ *Supra*, n 1, [57].

⁴⁸ *Ibid*, [57]. This paragraph is quoted by the Department of Health, *Reference Guide to Consent for Examination or Treatment*, 2009, ch.1, para.41. The issue is not addressed in GMC, *0-18 years: guidance for all doctors*, 2007.

Having concluded that the therapy was supported by a reasonable body of professional opinion capable of withstanding logical analysis, the next question was whether it was in the best interests of the teenagers. Butler-Sloss P stressed that best interests had to be assessed in the 'widest possible way',⁴⁹ 'to include the medical and non-medical benefits and disadvantages, the broader welfare issues of the two patients, their abilities, their future with or without treatment, the views of the families, and the impact of refusal of the applications.'⁵⁰ Whilst there were risks involved in the therapy and its administration, a 'slightly longer life' within their 'devoted and wonderfully caring famil[ies]' was a benefit worth having.⁵¹ Butler-Sloss P gave the views of the parents and the 'effect upon them of refusal great weight in the wider considerations of the best interests test' recognising the 'agony' they had gone through in witnessing the deterioration of their children and their deep commitment to the therapy.⁵² Butler-Sloss P emphasised that the parents understood the risks, were aware of the uncertainty of benefit and would not prolong life if their child was suffering. The balance of research and expert evidence before the court supported the conclusion that the therapy should be tried, a conclusion shared by the Official Solicitor.

In an Appendix added to the judgment on the day it was published, Butler-Sloss P explained that although the court had declared the treatment lawful and the consultant neurosurgeon in responsible for the teenagers was prepared to try it, the Trust's Clinical Governance and Quality Committee refused to approve the provision of the treatment at the hospital and the chair of the Drugs and Therapeutic Panel had indicated it would not approve the administration of the drug.⁵³ The consequence, Butler-Sloss P said, was that the proceedings had been an 'unacceptable academic exercise' which was a 'cruel blow' for the families. Acknowledging that the application to court had been made by the parents, the judge expressed the hope that in future cases a Trust would 'form its own conclusions' about the administration of therapy before the matter was referred to court.⁵⁴ However, as the judge had requested in her judgment, the Department of Health assisted the families by investigating other possibilities for the provision of the therapy.⁵⁵ A hospital in Northern Ireland was prepared to provide the therapy, which it did after approval from the Northern Ireland High Court.⁵⁶

To illustrate the argument that *Simms* provides a better framework for decisions about the provision of innovative therapy to children, than one based upon best interests alone, I now address each of the questions posed in *Simms* applying them to the facts in Charlie's case.

Did Charlie have the capacity to make decisions about his medical treatment?

It was agreed that Charlie, six months old at the time of the application, lacked the capacity to make decisions about his medical treatment. His parents had been making decisions, from the treatment options presented to them by his clinicians, in the exercise of parental responsibility. Whilst they retained their parental responsibility, once the application was before the court it was the responsibility of the judge, Francis J, to decide upon the specific issues in the application.

⁴⁹ *Ibid*, [60].

⁵⁰ *Ibid*, [60].

⁵¹ *Ibid*, [61].

⁵² *Ibid*, [64].

⁵³ *Ibid*, [74].

⁵⁴ *Ibid*, [70].

⁵⁵ *Ibid*, [74].

⁵⁶ Owen Dyer, 'Family finds hospital willing to give experimental CJD treatment' (2003) 326 BMJ 8. At the time average life expectancy from initial onset of symptoms was 14 months, *Donald Simms and Jonathan Simms v An NHS Trust and Secretary of State for Health; PA and JA v An NHS Trust and Secretary of State for Health* [2002] EWHC 2734, [9] Jonathan Simms lived another ten years.

Was there a responsible body of medical opinion which would support the treatment?

The evidence before the High Court in April was that nucleoside bypass therapy had not been given to anyone with Charlie's condition, RRM2B, nor tested upon mice with this mutation. It had been used with patients with a less severe mitochondrial condition, the TK2 mutation. A key difference between the two conditions was that to be beneficial with RRM2B the drugs would have to cross the blood/brain barrier enabling it to work on the brain in the same way as the rest of the body,⁵⁷ of which there was 'theoretical and anecdotal', but no direct, evidence.⁵⁸ One competent body of professional opinion held by the clinicians at GOSH, supported by second opinions, was that given that Charlie had suffered severe brain damage trial of the therapy was not a proper course of medical treatment. As Francis J observed Professor Hirano, one of the experts in a highly specialised field, was a 'lone voice' in his willingness to try the therapy.⁵⁹ The court did not have evidence before it of a responsible body of medical opinion prepared to try the therapy.

It was agreed that the administration of the therapy itself, a powder mixed into food, presented little risk. The prospect of benefit was, Francis J concluded from the evidence before him, 'as close to zero as makes no difference', in other words, he said, it would be 'futile'.⁶⁰ At the April hearing, Professor Hirano agreed with Charlie's treating clinicians that the therapy was 'unlikely' to 'help Charlie's severe neurological disease'⁶¹ but was prepared to try as it was the only option and without it Charlie's condition was fatal.⁶² In his April judgment, Francis J noted that although Professor Hirano had been given access to Charlie's medical records and had seen the latest EEG he had not examined Charlie.⁶³ Professor Hirano's lack of direct knowledge of Charlie's current condition was evident in his response to the question whether he was aware that the Trust's primary application was with respect to the withdrawal of ventilation. He said, 'Perhaps, if I were there, I would support it. Not seeing the child, not seeing progression, it's difficult for me to make an assessment'.⁶⁴ As Counsel for Charlie's Guardian, Victoria Butler-Cole, stated:

'If novel therapies are to be offered, it appears to the Guardian to be imperative that those offering to provide them are fully aware of the clinical condition and medical history of the particular patient and have had extensive discussion with the treating team, so that offers are made on an informed basis and without setting up false hopes and expectations.'⁶⁵

As Francis J explained in his July judgment, the court could not rely upon the evidence of a doctor from another hospital who had not examined Charlie, his medical records, or the second opinions obtained by GOSH.⁶⁶ An opinion formed without such examination could not withstand logical analysis. The evidence before the court in April amounted to a 'theoretical' possibility that the therapy could be of benefit for which there was no clinical evidence.⁶⁷ Unlike in *Simms* there was no competent body of professional opinion before the court prepared to try the therapy. Yet, the US doctor's continued willingness to try the therapy kept alive the hopes of Charlie's parents that there was a chance of an improvement to his quality of life, if only Professor Hirano were allowed to try it.

⁵⁷ *Supra*, n 4, [73].

⁵⁸ *Ibid*, [76], [101].

⁵⁹ *Ibid*, [16].

⁶⁰ *Ibid*, [119].

⁶¹ *Ibid*, [75].

⁶² *Ibid*, [127].

⁶³ *Ibid*, [94], [98].

⁶⁴ *Ibid*, [99].

⁶⁵ Guardian position statement, 24 July 2017, [7] <https://www.serjeantsinn.com/news/charlie-guard-position-statements/> [last accessed 27/9/17].

⁶⁶ *Supra*, n 23, [12].

⁶⁷ *Supra*, n 4, [101].

In July Counsel for Charlie's parents, Grant Armstrong, submitted that they had new evidence about the therapy which meant there was a competent body of professional opinion which supported its provision. At the invitation of Francis J, Professor Hirano agreed to come to London to examine Charlie and discuss his condition and any viable therapy with the GOSH clinicians. At this multidisciplinary meeting it was agreed that Charlie would undergo further tests. An MRI body scan revealed the extent of muscle deterioration which led Charlie's parents, in consultation with Professor Hirano, to the conclusion that the therapy 'no longer offers a chance of a meaningful recovery to Charlie'.⁶⁸ Having examined Charlie, his medical records and discussed the latest test results all experts were in agreement with the conclusions of his clinicians at GOSH. Throughout the proceedings there had been no competent and reasonable body of professional opinion in the UK, Europe or the world, which supported the trial of the therapy. The absence of a competent body of medical opinion considering the therapy to be proper medical treatment would, following the approach in *Simms*, have led to the declarations sought by GOSH being made. Thus, on the facts of the case, adopting the approach applied in *Simms* would not have led to a different outcome. To have addressed directly the question whether the therapy was supported by a competent and reasonable body of professional opinion would have identified, at an earlier stage in the proceedings, the absence of the medical evidence the court required before it could agree to the innovative therapy.

Was it in Charlie's best interests to have the therapy?

For Charlie's clinicians at GOSH, having concluded that trial of the therapy was not one they could in their professional judgment administer to Charlie, the question was whether it was in his best interests to be kept alive on ventilation. Patients who have been mechanically ventilated and recovered have told of the pain and suffering it caused them. Charlie's clinicians believed he had a conscious experience of pain which he was unable to express.⁶⁹ Their professional conclusion was that Charlie's 'current quality of life is not one that should be sustained without hope of improvement' and therefore he should not be subjected to more pain and suffering for the administration of 'futile' therapy.⁷⁰ However, had there been evidence before the court of a body of 'responsible medical opinion' which did not 'reject the research'⁷¹ there would then have been two viable options supported by competent professional opinion. The next question would have been which of these two alternatives, withdrawal of active treatment and the provision of palliative care to ensure a dignified and peaceful death or the continuation of ventilation and trial of innovative therapy, was in Charlie's best interests.

Charlie's parents assessment of what was best for their son was based not only upon the hope maintained by the offer from the US doctor to administer the therapy but upon their experience and knowledge of their son as an individual gained through the hours they had spent with him at his bedside each day over the months he had been hospitalised. As Alderson et al noted, from their observations of premature babies in a neonatal intensive care unit, whilst unable to express themselves in words, babies "speak" in an expressive language of sounds, facial expressions and body movements that can be "read" by parents concerned to represent their child's views. Those caring for the babies described their unique characters and personalities as individuals enabling an assessment of best interests which is personal, particularistic and relational. Both parents and professionals reflected upon babies who had

⁶⁸ Position statement on behalf of the parents, 24 & 25 July, [19], <https://www.serjeantsinn.com/news/charlie-gard-position-statements/> [last accessed 27/9/17].

⁶⁹ *Supra*, n 4, [16].

⁷⁰ *Ibid*, [113-4].

⁷¹ *Supra*, n 1, [48].

fought for their life and those who appeared to have had enough.⁷² Charlie's parents did not accept his clinician's assessment of the extent of his brain damage believing that he responded to them, and was able to express pleasure and his dislikes.⁷³ They were driven by the view that he was fighting for his life and whilst he was still fighting they would fight for him.

Where parental decisions about their child's well-being made in the exercise of their parental responsibility are challenged before the courts best interests needs to be assessed, as Butler-Sloss P stated, in the 'widest possible way'.⁷⁴ This requires a focus upon the individual child with a 'body, mind and spirit expressed in a human personality of unique worth who is profoundly precious to her parents'⁷⁵ to which parental evidence is particularly relevant. Parents, like professionals, have specific expertise as to the best interests of a child which must be considered by a judge to fulfil the responsibility to reach an independent, objective, decision as to child welfare. The reasoning which the parents sought to employ in the exercise of their parental responsibility should be brought into the assessment of best interests at the same time ensuring that the decision is focused upon the interests of the child who is known best by those who care for him or her. The court will assess the parental evidence in the same way as it assesses the medical evidence. As Butler-Sloss LJ explained in *Re T* the duty of the court is to undertake an independent assessment of the welfare of the child in the context of all the relevant facts including the view of the child's parents - depending upon the court's assessment of those views.⁷⁶ Decisions have to be made about what is best for the child that all with responsibility for the child, parents, healthcare practitioners and judge, can live with.

When they believed that there was a viable alternative treatment offered by a specialist which gave their son a chance of a better quality of life, Charlie's parents understandably concluded it was best for him to try it. Other parents faced with this decision could equally have concluded that palliative care was in the best interests of their child. Agonising as Francis J recognised it was, following discussions with Professor Hirano in light of the results of the MRI test in July, Charlie's parents accepted that the therapy offered no chance of a better quality of life for Charlie and reluctantly agreed that the only course was the provision of palliative care.⁷⁷ Throughout, Charlie's parents were acting upon what they genuinely believed from their understanding of the evidence to be best for their son.

Was the therapy capable of being carried out within the NHS?

The GOSH clinicians had initially been prepared to try nucleoside therapy. They had in the past administered nucleoside therapy to children with other mitochondrial conditions so there were no issues of expertise, facilities, or special equipment. In comparison with the *King* case, where the treatment his parents wanted him to receive was not available in the UK,⁷⁸ the therapy could have been administered at GOSH with Charlie remaining on ventilation in intensive care whilst his progress was monitored. Neither, as Francis J observed in his April judgment was funding an issue, as it had been for the extra-contractual referral in the case of Jaymee Bowen or Ashya King's treatment abroad.⁷⁹

⁷² Priscilla Alderson, Joanna Hawthorne and Margaret Killen, 'The Participation Rights of Premature Babies', in Michael Freeman (ed), *Children's Health and Children's Rights*, Martin Nijhoff Publishers, 2006, 31-50, 34.

⁷³ *Supra*, n 4, [107-112].

⁷⁴ *Supra*, n 1, [60].

⁷⁵ *Portsmouth NHS Trust v Wyatt* [2004] EWHC 2247, [39].

⁷⁶ *Re T (a minor) (wardship: medical treatment)* [1997] 1 WLR 242, 250.

⁷⁷ *Supra*, n 23, [1].

⁷⁸ Proton Beam Therapy Centres are under construction; one at The Christie NHS Foundation Trust Manchester is expected to open in 2018 and one at University College London Hospital NHS Foundation Trust in 2020, <https://www.england.nhs.uk/commissioning/spec-services/highly-spec-services/pbt/> [last accessed 27/9/17].

⁷⁹ *Supra*, n 4, [80].

From April when Francis J made the declarations until the end of July when Charlie's parents accepted the evidence that palliative care was the only option, although the hospital had a court order which stated that it was lawful to withdraw ventilation and provide palliative care, Charlie remained on ventilation. In June, Lady Hale in the Supreme Court observed that, as a consequence of the stay of the declarations, it had been lawful for doctors to continue to ventilate Charlie. Ethically, however, the Justice observed, his doctors considered it wrong to have continued to do so contrary to their professional judgement that it was not in his best interests.⁸⁰ At the same time, his clinicians remained open to new evidence which would have enabled them to alter their professional judgement.

Had there been a different, competent, body of professional opinion which supported provision of the therapy and the judge been of the opinion that it was in Charlie's best interests to receive it, it is a well-established principle that neither the court nor parents can require doctors to treat contrary to their professional judgement. This was first stated by Lord Donaldson MR in the Court of Appeal in one of the first cases in which the withholding of life-sustaining treatment was before the court for consideration, *Re J (1990)*,⁸¹ repeated as part of his ratio in the case in *Re J (1992)*,

'The fundamental issue in this appeal is whether the court ... should ever require a medical practitioner ... to adopt a course of treatment which in the bona fide clinical judgment of the practitioner concerned is contra-indicated as not being in the best interests of the patient. I have to say that I cannot at present conceive of any circumstances in which this would be other than an abuse of power as directly or indirectly requiring the practitioner to act contrary to the fundamental duty which he owes to his patient. This, subject to obtaining any necessary consent, is to treat the patient in accordance with his own best clinical judgment, notwithstanding that other practitioners who are not called upon to treat the patient may have formed a quite different judgment or that the court, acting on expert evidence, may disagree with him.'⁸²

Lord Donaldson MR said in *Re J* that parents cannot insist on treatment and doctors can refuse to administer treatment which they consider to be medically contra-indicated or which they cannot conscientiously administer.⁸³

Hedley J gave further consideration to professional conscience in his fourth judgment in the case of Charlotte Wyatt. A year after the initial application by the Trust and in light of evidence of improvement in her condition, Charlotte's parents applied for a discharge of the declaration which authorised withholding of ventilation in the event of a respiratory attack, whilst the Trust made a 'novel' application for authority, in the event of an irreconcilable disagreement about her treatment, for decisions to be made by her doctors.⁸⁴ The relationship between her parents and the hospital had become volatile and acrimonious; her parents had made complaints to the police about Charlotte's care and were only permitted to visit her accompanied by security.⁸⁵ Hedley J discharged the declaration which had the effect of returning responsibility to consent to the provision or withholding of ventilation to Charlotte's parents. In these circumstances, Hedley J was concerned to explain clearly the nature and limits of the

⁸⁰ Supreme Court, *Judgment of the UK Supreme Court in the Case of Charlie Gard*, 19 June 2017, <https://www.supremecourt.uk/news/latest-judgment-in-the-matter-of-charlie-gard.html> [last accessed 27/9/17];

⁸¹ *Re J (A Minor) (Wardship: Medical Treatment)* [1991] Fam 33.

⁸² *Re J (A Minor) (Child in Care: Medical Treatment)* [1992] 3 WLR 507, 516 and again in *Re R (A Minor) (Wardship: Medical Treatment)* [1991] 4 All ER 177.

⁸³ *Supra*, n 81, 40.

⁸⁴ *Re Wyatt* [2005] EWHC 2293, [14].

⁸⁵ *Ibid*, [17-26].

professional duties doctors owe to their child patient. Hedley J stressed that where the patient lacks competence the doctor's duty is to act in the patient's best interests and to work in partnership with the child's parents,⁸⁶ accommodating parental wishes where to do so is not an 'affront to the clinician's conscience'.⁸⁷ But that, following *Re J* (1992), professionals cannot be required to act contrary to their professional conscience. This, Hedley J explained, was an 'intellectual' process in which the doctor must take account of all the circumstances, professional guidance and second opinions, to conclude what is in the patient's best interests.⁸⁸ Professional conscience is more intuitive than rational and 'honed by experience of patients, exposure to the practice of colleagues, and the ethos of his work'.⁸⁹ For the GOSH clinicians, given the deterioration in Charlie's condition, having followed the RCPCH Guidelines and secured second opinions from within the UK and Europe, administration of nucleoside therapy was not in accordance with a competent body of professional opinion and it would have been an affront to professional conscience to administer it to him. Where they reach this conclusion, clinicians have a duty to seek other doctors who may be willing to treat.⁹⁰ If there is a competent body of professional opinion prepared to administer treatment to a child, they will be able to locate a clinician prepared to do so.

Throughout the proceedings, Francis J encouraged the parties to resolve their differences so they could together agree what was best for Charlie. In his April judgment, the judge expressed the opinion that in all such cases an Issues Resolution Hearing or other form of mediation would at least enable the parties to explore whether there was any common ground.⁹¹ In the July hearings, whilst making authoritative rulings Francis J sought to facilitate agreement. The judge encouraged the parties to try mediation, facilitated the parties' agreement to an experts meeting chaired by an independent clinical ethicist and attended by Connie Yates, and encouraged the parties to explore all options to find end of life care upon which all could agree. The judge will not order doctors to treat contrary to their professional conscience but can encourage the parties to reach agreement upon the best interests of the child.

Jonathan Montgomery has argued that the judiciary have not been very exacting in establishing the standards the law imposes upon medical practice. He suggested that we should look instead to the values and standards within the professions set by, for example, good practice guidelines.⁹² The clinicians at GOSH had applied the RCPCH Guidance in reaching their conclusion that ventilation should be withdrawn and made reference to their duty to put the interests of the child first as stated in GMC guidance.⁹³ Good medical practice will also ensure that decisions are subject to proper scrutiny to protect the interests of the child.⁹⁴ The GOSH clinicians had planned to put the question of the administration of the

⁸⁶ *Ibid*, [29].

⁸⁷ *Ibid*, [30].

⁸⁸ *Ibid*, [34].

⁸⁹ *Ibid*, [36].

⁹⁰ *Ms B v An NHS Hospital Trust* [2002] EWHC 429 [100 (viii)], although a case concerned with the decisions of a competent adult, this must equally be so in the treatment of children who should not be denied treatment merely because they lack the capacity to decide for themselves. *Supra*, n 4, [130], repeated in his July judgment, *supra*, n 23, [20].

⁹² Jonathan Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition' (2000) 53 CLP 363-408. Although professional guidance may seek to set out what the law provides, Jose Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*, 2007. But see the framework proposed by Joe Brierley and Vic Larcher, 'Compassionate and innovative treatments in children: a proposal for an ethical framework' (2009) 94 Arch Dis Child 651-654, <http://nnpdf.org/files/2016/11/Compassionate-Use-in-Children.pdf> [last accessed 26/9/17].

⁹³ GMC, *0-18 years: guidance for all doctors*, 2007.

⁹⁴ For example, the World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, October 2013, para. 37 provides that innovative treatment is ethically justified where proven interventions do not exist, the clinician has sought expert advice, secured informed consent from someone with authority to give it and in the

innovative therapy to their Ethics Committee and, where treatment in the US was planned, the therapy required US Food and Drug Administration approval for first use in humans. Not all cases will end up in court. The parents of Charlie, Ashya and Jaymee are not the only ones who have fought for their child to have a chance of innovative therapy. Similarly, cases in which parents are agreed with their child's clinicians that active treatment is no longer in their child's best interests may not be referred to court. Whether before the court or not, the standards the law imposes are supplemented by good medical practice which serves to protect both practitioner and patient.

Conclusions

In most cases parents are asked to give their consent to treatment with known therapeutic benefits, or to agree to the withholding or withdrawal of active treatment, recommended by clinicians in the exercise of their judgement in accordance with a competent body of professional opinion. Where disagreements about a child's medical treatment are brought to court and the focus is upon the question of the child's best interests, it is assumed that the treatment option under consideration is proper medical treatment for the child. The case of Charlie Gard required explicit assessment of the question whether there was a competent body of professional opinion which supported the trial of innovative therapy. With easy access to information, of varying degrees of veracity, of possible alternative treatment via the internet the viability of alternative therapy is increasingly going to be an issue for debate between parents of seriously ill children and their clinicians both seeking to ensure the child receives the best possible medical treatment. Concerned as all courts were with the sole question of what was in Charlie's best interests, the judgments of the courts from the Family Division in April, through the domestic appeals process, to the European Court of Human Rights and back to the High Court in July, do not provide any guidance for those who may in the future be faced with a disagreement about what is medically possible. The answer I argue lies in the framework set out in *Simms*: considering professional duties of care in the determination of competent and reasonable body of professional opinion, determination of the best interests of the child informed by parental knowledge and expertise gained as they care for their child and good medical practice guidance and processes to ensure the child is given the best possible care but is not exposed to harm by pioneering, novel, or experimental, therapy.

Whilst in July, Charlie's parents reluctantly agreed that it was no longer in Charlie's best interests to try the therapy and withdrew their opposition to the orders⁹⁵ they maintained the view that had Charlie received the therapy at an earlier point in time it would have made a difference. They maintained the view that had they been able to secure what they considered to be in their son's best interests he would have had a chance of a better quality of life. Although necessarily speculative, had there been a thorough review of proper medical treatment, it is possible that an agreement may have been reached between Charlie's parents and clinicians at an earlier stage. An earlier agreement would have prevented the distress caused to the parents by the lengthy court proceedings in which they no longer were able to make decisions about their child's life. An earlier agreement could have limited the deterioration to the parent/professional relationship and the period of time during which the clinicians were legally obliged to continue ventilation when they considered this to be professionally and ethically wrong. Most significantly, it could have facilitated an earlier agreement about the future medical treatment that was best for a seriously ill child by those most directly responsible for his welfare.

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clinical judgement of the clinician the intervention offers 'hope of saving life, re-establishing health or alleviating suffering', <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [last accessed 26/9/17].

⁹⁵ Position statement on behalf of the parents, 24 & 25 July, [24] <https://www.serjeantsinn.com/news/charlie-gard-position-statements/> [last accessed 27/9/17].